EXHIBIT 27

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF CARDINAL HEALTH	)	**Docket No. 12-32**
	)	**Administrative Law Judge Gail A. Randall**

DECLARATION OF MICHAEL A. MONÉ
PURSUANT TO 28 U.S.C. § 1746

I, Michael A. Moné, declare as follows:

1. I am the Vice President for Supply Chain Integrity of Respondent Cardinal Health, Inc. ("Cardinal Health"). I hereby submit this Declaration setting forth my direct testimony in this matter on behalf of Cardinal Health. I have personal knowledge of the facts set forth herein or believe them to be true based on my experience or upon information provided to me by others.

I. Background and Experience

2. I am a trained and licensed attorney and pharmacist. I graduated from the University of Florida College of Law in 1985 with a Juris Doctor degree. I graduated from the University of Florida College of Pharmacy in 1981 with a Bachelor of Science in Pharmacy degree. I am admitted to the Florida Bar and am registered as a pharmacist in the states of Florida, Texas, and Ohio. I was the Executive Director of the Kentucky Board of Pharmacy from September 1996 to January 2004. I was an Assistant Attorney General in the State of Florida from August 1993 to August 1996. As an Assistant Attorney General, I represented the Boards of Chiropractic, Osteopathic, and Veterinary Medicine, providing legal advice to these boards about the application of the statutes governing the admission, fitness to practice, and discipline of practitioners who fell below professional standards. From January 1987 to November 1991, I was a trial and appellate attorney for the Florida Department of Professional Regulation. In that

role, I represented the Board of Pharmacy and prosecuted administrative cases against pharmacies and pharmacists who engaged in dispensing prescriptions for controlled substances that were not issued for legitimate medical purposes. I also assisted in the determination of probable cause for the discipline of practitioners who prescribed and dispensed controlled substances. I am currently serving a four-year term (2010-2014) as a member of the Ohio Board of Pharmacy.

3. I have held the position of Vice President for Supply Chain Integrity for Cardinal Health since December 2007. In this role, I modified Cardinal Health's anti-diversion program that existed in December 2007 to comport with the DEA's letters to distributors dated December 27, 2007, informing them that, in addition to detecting and reporting suspicious orders in accordance with 21 C.F.R. § 1301.74(b), a distributor must not fill "suspicious orders" unless the distributor determines that the controlled substances are not likely to be diverted into illegitimate channels. Under my supervision and guidance, Cardinal Health has continuously improved its anti-diversion program and adapted it to the ever-changing nature of diversion.

4. I report directly to Gilberto Quintero, a Senior Vice President of Quality and Regulatory Affairs for Cardinal Health. I ultimately report to Cardinal Health's Chief Legal and Compliance Officer, Craig Morford.

II. Distributors' Role And The History Of Anti-Diversion Of Controlled Substances

A. The Closed Distribution System And History Of Regulation

5. In the closed distribution system for controlled substances, wholesale distributors such as Cardinal Health interface exclusively with DEA-registered entities: They purchase controlled substances from DEA-registered manufacturers and they sell those controlled substances to DEA-registered customers.

6. As a result of the wholesale distributors' unique position along the supply chain, historically and today, very little diversion comes directly from wholesale distributors. By and large, wholesale distributors have been directly responsible for the diversion of controlled substances only where (1) they distributed outside the closed distribution system; or (2) controlled substances in their possession were diverted due to theft, breaches of physical security, or criminal conduct by their employees.

7. That distributors were rarely the source of diversion was well understood in the healthcare industry. A 2005 survey conducted by the National Center on Addiction and Substance Abuse at Columbia University for a major study of the "diversion problem" concluded that only 0.9% of pharmacists and 0.5% of physicians identified drug wholesalers as "account[ing] for *most* of the diversion problem." Respondent Exhibit ("Resp. Exh.") 70 at 119, 137 (emphasis in original).[1]

8. Instead, the vast majority of diversion has happened at the doctor or pharmacy stage of the distribution system, where DEA-registered doctors and DEA-registered pharmacists interact with *non*-DEA-registered patients. In the study mentioned above, the physicians and pharmacists surveyed ranked patients, physicians, Internet pharmacies, and retail pharmacies higher as a source of diversion than wholesale distributors. *Id.* at 119, 137 (patients identified as most accountable by approximately 52% of pharmacists and 59% of physicians; Internet pharmacies identified by approximately 15% of pharmacists and 8.6% of physicians; physicians identified by 9.7% of pharmacists and approximately 12% of physicians; retail pharmacies identified by 8.5% of pharmacists and 3.1% of physicians).

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[1] All Cardinal Health exhibits referenced in this declaration are true and correct copies of the documents at issue.

9. Before 2005, DEA focused on the doctors who were writing illegitimate prescriptions and the pharmacists who were filling them. To the best of my knowledge, until 2005, regulators did not articulate an expectation that distributors actively conduct due diligence regarding their downstream customers beyond the reporting of suspicious orders pursuant to 21 C.F.R. § 1301.74(d). Rather, regulators principally expected distributors (1) to ensure that they were operating exclusively within the closed distribution system by checking the registration status of their customers (hospitals, pharmacies, dispensing doctors), and (2) to prevent theft and physical diversion of controlled substances from their facilities or in the course of shipping.

10. To the best of my knowledge, Cardinal Health has not distributed any controlled substances to any pharmacy that did not have an active, valid registration with DEA at the time of distribution. Furthermore, Cardinal Health's Distribution Centers make great efforts to prevent any theft of controlled substances or security breaches in their handling of those substances.

11. The advent of the Internet introduced a new method of potential diversion through "Internet pharmacies." As DEA has interpreted the term (and as the term is used in this declaration), an "Internet pharmacy" is a pharmacy that

> fills a prescription that is issued by the physician without the physician having entered into a legitimate doctor-patient relationship under existing professional standards. Typically, a person seeking controlled substances goes to an internet site, fills out a questionnaire which requests basic medical information and payment/shipping information, and requests a specific drug; some Web sites may require that the patient submit a medical record, which is easily falsified. Thereafter, the customer's information is forwarded to a physician either contracted to or employed by the Web site, who reviews the information and issues a prescription, either with or without the benefit of a perfunctory telephone consultation, but always without having conducted a face-to-face review of the person's medical history and a physical exam. The prescription is then either forwarded to the pharmacy or

> downloaded electronically by the pharmacy; the pharmacy then fills the prescription and ships it to the customer.

Southwood Pharms., Inc., 72 Fed. Reg. 36,487, 36,488 n.2 (DEA July 3, 2007).

12. During the first half of the last decade, the number of Internet pharmacies increased substantially. This new, Internet-based method of diversion took regulators by surprise. To respond to Internet pharmacy-based diversion, DEA began for the first time to direct distributors to actively conduct due diligence regarding their downstream customers. DEA first communicated this new directive to distributors through informal meetings in 2005 and 2006. Resp. Exh. 71 contains a copy of materials provided by DEA to Cardinal Health at one such meeting in August 2005. DEA then issued a series of letters relating to DEA's expectations in 2006 and 2007. *See* Resp. Exhs. 8, 9, 10, 11.

13. Wholesale distributors were initially caught by surprise as well. Distributors had developed anti-theft, physical-security, and registration-verification protocols; by the mid-2000s, however, they arguably lacked the expertise to conduct effective independent due diligence of their downstream customers. DEA then began bringing enforcement actions against distributors. In late 2006, DEA brought an enforcement action against Southwood Pharmaceuticals, which resulted in the Administrator's decision in *Southwood*. DEA also initiated actions against two major drug distributors, McKesson Corp. and AmerisourceBergen Corp. In December 2007, DEA initiated an enforcement action against Cardinal Health by issuing Immediate Suspension Orders ("ISOs") against three Cardinal Health distributions centers. DEA then issued an Order to Show Cause against a fourth Cardinal Health distribution center. The ISOs against Cardinal Health distribution centers principally related to sales to Internet pharmacies. To settle and resolve the 2007 administrative actions against it, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("MOA") with DEA in

2008. *See* Resp. Exh. 62. Cardinal Health's Lakeland facility resumed distributing controlled substances in the fall of 2008. *See, e.g.*, Resp. Exh. 38 (DEA's ARCOS data for pharmacies named in the February 2, 2012 immediate suspension order, which shows no distribution of controlled substances until November 2008).

14. Once downstream oversight structures were put in place, the task of identifying and terminating Internet pharmacies was relatively straightforward. With Internet pharmacies, a wholesaler could reach the conclusion that a customer presented an unreasonable risk of diversion on the basis of objectively verifiable indicia. This is because a site visit and, in some instances, even an Internet search would allow a wholesaler to determine that the prescriptions filled by an Internet pharmacy were likely to have been obtained pursuant to an illegitimate doctor-patient relationship. Several factors could provide objective—and conclusive—evidence that the pharmacy was filling illegitimate prescriptions, including: (1) the pharmacy's solicitation of buyers of controlled substances via the Internet or (2) its facilitation of the acquisition of prescriptions for controlled substances from physicians with whom the buyer had no preexisting relationship.

15. Even when such direct evidence was unavailable, the indicia of Internet-based diversion were often apparent. For example, there would have been no reason—other than the pharmacy's willingness to fill illegitimate Internet-based prescriptions—why the following indicia should be found at the site of a community pharmacy: (1) numerous boxes used to ship controlled substances to patients with whom the pharmacist or doctor could not have interfaced in person; (2) unreasonably low number of patients filling prescriptions in person; (3) large numbers of computer screens and fax machines at the site of the pharmacy.

16. Ultimately, Congress addressed the problem of Internet pharmacies by enacting the Ryan Haight Act. Among other reforms, the Ryan Haight Act (1) required Internet pharmacy websites to display information identifying the business, pharmacist, and physician associated with the website; and (2) barred the selling or dispensing of prescription drugs via the Internet when the website has referred the customer to a doctor who then writes a prescription without ever seeing the patient. *See* Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820, §§ 2-3. These disclosure and regulatory requirements—coupled with distributors' independent oversight—significantly undermined the ability of U.S.-based Internet pharmacies to divert controlled substances.

17. As diversion from Internet pharmacies declined, certain medical practices purporting to operate as "pain clinics" emerged as a major source of diversion. These "pain clinics" were typically not DEA registrants and did not order from distributors directly. Rather, they were facilities where one or more DEA-registered doctors used their own DEA registrations to order controlled substances from distributors and then dispensed those drugs directly to patients pursuant to prescriptions that were not issued in good faith, in the course of professional practice, and for a legitimate medical purpose.[2]

18. In June 2010, Florida enacted a law intended to address the illegitimate dispensing of controlled substances by pain clinics. The enactment prohibited physicians from "dispens[ing] more than a 72–hour supply of a controlled substance … for any patient who pays for the medication by cash, check, or credit card in a [pain management] clinic." Fla. Stat.

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[2] To be clear, not all pain management practices operate as described in paragraph 17. Many pain management practices are entirely legitimate medical facilities where controlled substances are prescribed, dispensed, or administered in good faith, in the course of professional practice, and for a legitimate medical purpose. For purposes of this declaration, however, I use the term "pain clinic" to refer only to the subset of pain management facilities that operate in the illegitimate fashion described in paragraph 17, unless otherwise specified.

§ 465.0276(1)(b) (2010) (amended by 2011 Fla. Sess. Law Serv. Ch. 2011-141). Under the law, physicians were prohibited from dispensing large amounts of controlled substances directly to certain patients at pain management facilities. But these physicians still maintained valid DEA registrations, which allowed them to continue writing prescriptions for controlled substances. As a result, their patients generally shifted to traditional pharmacies for filling their prescriptions. The law took effect on October 1, 2010.

19. In June 2011, Florida further restricted the ability of physicians to dispense controlled substances. The 2011 law became effective on July 1, 2011 and barred, with a few exceptions, Florida physicians from dispensing Schedule II and Schedule III controlled substances in their offices or clinics. Fla. Stat. § 465.0276(1)(b) (2011) (codifying 2011 Fla. Sess. Law Serv. Ch. 2011-141).

B. Challenges Currently Faced By Distributors In Their Struggle Against Diversion

20. As a result of the laws enacted by Florida in 2010 and 2011, a large volume of demand for controlled substances in Florida migrated from pain management facilities—where physicians previously dispensed controlled substances directly to their patients—to ordinary brick-and-mortar pharmacies. Notably, because the Florida laws apply to both legitimate pain management facilities and illegitimate "pain clinics," only an unknown portion of the volume formerly dispensed directly by physicians was the result of illegitimate prescriptions. It thus became incumbent on the pharmacists at traditional pharmacies to discern whether the prescriptions that migrated to a particular pharmacy were written for an illegitimate medical purpose.

21. The task confronting Florida pharmacists is complex. As DEA has recognized in the context of law enforcement, "[a] tremendous challenge … when dealing with pharmaceutical

controlled substances is often distinguishing among legitimate medical uses and illegal uses." Resp. Exh. 20 at 2.

22. The second-order task of wholesale distributors servicing those pharmacies—i.e., detecting diversion from brick-and-mortar pharmacies—is even more challenging. Patient privacy concerns preclude prescribing practitioners and dispensing pharmacies from providing patients' prescriptions or medical records to distributors. Distributors thus cannot directly observe if a valid physician-patient relationship exists because they: (a) cannot be present during the physical examination of a patient; (b) do not have access to prescriber records concerning that patient; and (c) are not privy to other interactions that take place between those parties as they relate to prescribing decisions made for that patient. Furthermore, brick-and-mortar pharmacies, unlike Internet pharmacies, rarely offer any direct evidence of the illegitimacy of the underlying prescription, such as facilitation of a phony doctor-patient relationship or absence of direct contact between the pharmacy and the patient.

23. Instead, distributors must rely on indirect indicia suggesting that a pharmacist might be willing to fill (or unable to detect) an illegitimate prescription if he is presented with one. There are of course some indicia that *may* be consistent with a risk of diversion—for example, a high overall volume of sales of controlled substances, a high ratio of controlled substances purchased to other prescription drugs, a high incidence of cash payments for controlled substances, or the frequent presence of out-of-state vehicles in the pharmacy's or an adjacent parking lot. But these factors are rarely conclusive of diversion; in many instances, there are legitimate reasons for them. For example, a pharmacy located in close proximity to an oncology practice can legitimately be expected to fill larger volumes—and a higher ratio—of controlled substances than a pharmacy filling prescriptions written by general practitioners in a small town.

Cash payments can legitimately be expected to be more prevalent in an economically depressed area, where more patients are uninsured. And out-of-state vehicles are not surprising in the proximity of large interstate highways or where tourism is high. In short, wholesale distributors attempting to detect diversion at brick-and-mortar pharmacies are often confronted with inconclusive—and sometimes inconsistent—evidence.

C. Distributors Lack Access To Essential Data And Information To Fight Diversion

24. In an effort to more effectively meet these challenges, distributors and their trade association have asked DEA to provide data that would allow distributors to discern customers who are engaged in practices that are indicative of diversion. Specifically, distributors have requested information about (1) their customers' aggregate quantities of controlled substances and (2) the number of distributors from whom their customers purchase controlled substances. *See* Resp. Exh. 25 at 10; Resp. Exh. 27 at 2. DEA has access to this information because all distributors report the distribution of Schedule II controlled substances and Schedule III narcotics drugs to DEA through DEA's Automated Reports and Consolidated Orders System ("ARCOS"). This data would be helpful to distributors because it might, in at least some instances, expose a customer's attempt to elude its distributors' control systems. To avoid any objectionable sharing of confidential trade information, the data could be blinded so that the wholesaler that receives the data would not be able to determine which specific other wholesalers were supplying specific customers.

25. The distributor trade association has asked for this information, but DEA has declined to provide it, at least in part on the ground that it is confidential business information. DEA has, however, shared similar data with manufacturers. I understand that, at a recent meeting, Mallinckrodt, a manufacturer of pharmaceuticals including oxycodone, indicated that the

material that it had provided to Cardinal Health and other wholesalers in the past was ARCOS data provided to it by DEA.

26. Recent cooperation between Mallinckrodt and Cardinal Health demonstrates the benefits of information-sharing. In the fall of 2011, Mallinckrodt provided Cardinal Health with information suggesting that certain Cardinal Health pharmacy customers were purchasing oxycodone drugs from multiple distributors. In response to this information, Cardinal Health reviewed the customers Mallinckrodt identified. The new information enabled Cardinal Health to identify when a customer was being deceitful by indicating it did not purchase controlled substances from other suppliers. At my request, Mallinckrodt agreed to continue cooperating with Cardinal Health.

27. While the data provided by Mallinckrodt is a helpful step in the right direction, it cannot substitute for the more complete ARCOS data possessed by DEA. Unlike Mallinckrodt's sales data, DEA's ARCOS data covers all manufacturers. Blinded ARCOS data would thus permit Cardinal Health to obtain a complete picture of all the controlled substances ordered by Cardinal Health's pharmacy customers.

28. In October 2011, Cardinal Health's Chief Legal and Compliance Officer also requested that DEA provide Cardinal Health with any information it possessed indicating that any Cardinal Health customer was engaged in diversion. Cardinal Health promised immediately to cease distributing controlled substances to any customer DEA so identified. *See* Resp. Exh. 35. In December 2011, Cardinal Health again requested, through its outside counsel, that DEA inform Cardinal Health of any Cardinal Health customer that DEA believes is likely engaged in diversion. *See* Resp. Exh. 36.

29. DEA declined to provide the requested information. In the past, however, DEA had initiated this type of cooperation. On at least one occasion, DEA had recommended that Cardinal Health investigate a specific pharmacy. In July 2011, DEA Group Supervisor Ruth Carter advised me that Cardinal Health should investigate a pharmacy in Alaska that she specifically identified. I personally undertook the suggested investigation. In an e-mail to Ms. Carter dated October 18, 2011, I described my visit to the pharmacy and explained why I had concluded that the pharmacy presented a low risk of diversion. *See* Resp. Exh. 29.

III. Cardinal Health's Anti-Diversion Efforts

30. Cardinal Health is committed to preventing diversion of controlled substances. After the 2007 DEA enforcement actions against it, Cardinal Health recognized that it needed to improve its systems for identifying and preventing diversion of controlled substances into other than legitimate medical channels. Through investment, innovation, and training, Cardinal Health has built a robust real-time monitoring and investigation program.

31. I am the principal architect of Cardinal Health's suspicious order monitoring ("SOM") system. There are three primary components to the system: the "Know Your Customer" ("KYC") component, electronic monitoring of controlled substances orders, and investigations of customers. The first two components are the subject of testimony from other Cardinal Health witnesses. I will discuss the site visits conducted by Cardinal Health as part of the investigations component as well as Cardinal Health's reporting of suspicious orders. Select standard operating procedures describing Cardinal Health's SOM system are provided in Resp. Exh. 40.

A. On-Site Investigations

32. Historically, most site visits conducted by Cardinal Health have involved retail independent pharmacies. When a QRA pharmacist refers a retail independent pharmacy

customer for an on-site investigation, a QRA investigator is tasked with conducting the site visit. Cardinal Health's QRA investigators are trained in conducting such interviews, and most of them have law enforcement or regulatory investigation experience.

33. In preparation for the site visit, the QRA investigators are expected to review the customer's due diligence file in detail. This preparatory work may also include consultation of publicly available information about the pharmacy, its owner, and the locality in which the pharmacy is located.

34. Once on site, the QRA investigator conducts the investigation and updates the information about the customer using an investigative questionnaire that is based upon the "Know Your Customer Questionnaire." The investigator typically also interviews the pharmacist in charge of the pharmacy and/or, infrequently, the owner of the pharmacy, to the extent the owner is not himself or herself a pharmacist. This interview is aimed at collecting information that may be germane to the assessment of potential diversion.

35. In addition, Cardinal Health's QRA investigators consider a variety of additional factors, which may include, but are not limited to:

- the volume of controlled substances ordered;
- the methods of payment accepted by the customer;
- the incidence of various methods of payments;
- the percentage of transactions that do not include some form of third-party payment;
- the percentage of Schedule II controlled substances dispensed relative to all controlled substances;
- the percentage of controlled substances dispensed relative to non-controlled substances;

- the pharmacy's actual drug dispensing history; and
- the location, specialty, and disciplinary history of the top prescribers of controlled substances whose prescriptions are filled by the pharmacy.

36. The investigator makes a recommendation to the head of the QRA investigations team and files an investigative report in the customer's QRA file. Under the current rating system, investigators recommend that QRA review the customer in 12 months, 3 months, or immediately; under the rating system used by Cardinal Health until recently, investigators recommended that the customer be classified as a low, medium, or high risk of diversion. Customers are not informed of the content of the investigative report or of the QRA investigator's recommended rating.

37. When an investigator's report and/or recommendation requires additional review, they are reviewed by a QRA pharmacist. The QRA pharmacist may approve the rating recommended by the investigator, may request additional information from the pharmacy, may request an additional site visit, may reject the investigator's recommendation, or may take a combination of any of these actions.

38. For chain pharmacies, Cardinal Health's policy historically has been to rely on the chain's corporate office to provide information in response to investigations. That is because these chain pharmacies pose different levels of risk of diversion from retail independent pharmacies. A pharmacist at a chain store generally does not directly share in the pharmacy's profits and thus does not have the same financial incentives as a retail independent pharmacist when filling prescriptions. Furthermore, chain pharmacies can reasonably be assumed to have greater safeguards in place to monitor and prevent potential diversion, such as anti-diversion and

loss prevention programs. These chains include the likes of Walgreens, CVS, or Kroger—very large companies with the resources and incentives to try to prevent diversion.

39. As a result of these differences, it is not uncommon for wholesale distributors to employ similar but somewhat distinct procedures for chain pharmacies and retail independent pharmacies. For example, on September 11, 2007, DEA sponsored a presentation of an exemplary anti-diversion system by another distributor in which the presenter noted that the distributor did not conduct due diligence when opening accounts for individual chain pharmacies. DEA reported that feature of this model system on its website. *See* Resp. Exh. 14 at 7; Resp. Exh. 15 at 2.

40. DEA's own enforcement history confirms the reasonableness of applying similar but distinct due diligence models to chain pharmacies and independent retailers. When DEA took action against CVS 219 and 5195, DEA officials were quoted as saying that those ISOs were the first time stores in a national pharmacy chain had been the targets of suspension orders used to combat Florida's prescription drug abuse problem. *See* Resp. Exh. 72 (quoting Mark Trouville, Special Agent in Charge of DEA's Miami field office).

41. Recently, however, Cardinal Health has begun conducting site visits at chain pharmacies when deemed appropriate. In some instances, site visits to chain pharmacies will be similar to the site visits traditionally conducted by Cardinal Health's QRA investigators at independent retail pharmacies, which I have already described herein. In other instances, site visits to chain pharmacies will be conducted without making the pharmacy personnel aware of the purpose of the investigator's presence. This type of visit is intended to provide information to Cardinal Health that is used to supplement the information that Cardinal Health receives about the store from the chain pharmacy's corporate office.

B. Suspicious Order Reporting And DEA's Knowledge Thereof

42. When a customer's order for controlled substances would exceed a monthly threshold, Cardinal Health's policy is to hold the order and refer it to a QRA pharmacist for detailed review. Similarly, when an order is flagged as an "Order of Interest" for any other reason, that order is referred to the QRA pharmacist for detailed review. Until recently, it was Cardinal Health's policy to report orders as suspicious only after a QRA pharmacist had conducted a detailed review and concluded the order was truly "suspicious."

43. In early 2009, DEA inspected several distribution centers and reviewed Cardinal Health's SOM program under Cardinal Health's 2008 MOA with DEA. As part of this process, in January 2009, I met with employees of DEA, including Barbara Boockholdt, Chief, Regulatory Sections, Office of Diversion Control, to show them the SOM system. Ms. Boockholdt has been the designated DEA point of contact for matters relating to the MOA. My team and I explained to DEA personnel how Cardinal Health reported suspicious orders under its system—whereby orders are reported to DEA only if the QRA department concludes that the order is truly "suspicious" following a detailed investigation. DEA officials raised no objections to Cardinal Health's approach to suspicious order reporting during this meeting.

44. Cardinal Health's reliance on the professional judgment and detailed review of trained QRA pharmacists—as opposed to rigid formulas—to identify suspicious orders is consistent with DEA's directives. DEA has advised distributors against deluging DEA with reports of orders that are simply large. *See* Resp. Exh. 10 at 2; Resp. Exh. 12, slide 9. Because Cardinal Health's approach entailed a detailed review by QRA pharmacists, it was less likely to result in large numbers of false positives. Moreover, a presentation by Staff Coordinator Leonard Levin noted that a distributor should never fill a suspicious order. *See* Resp. Exh. 12, slide 9. It would seem inconsistent with Mr. Levin's instruction to implement a system where

orders that have been held pending investigation are immediately reported as suspicious and yet may later be released to the customer upon detailed review. Finally, Cardinal Health's approach is consistent with DEA's assertions that the decision to ship an order rests with the distributors, and that distributors must define their own parameters for suspicious orders. *See, e.g.*, *id.*, slide 10.

45. Since learning of DEA's investigation, Cardinal Health has reviewed its process for detecting and reporting suspicious orders. Out of an abundance of caution, Cardinal Health has recently implemented a modification of its suspicious order reporting process, which has resulted in increased reporting of suspicious orders.

C. Effectiveness of Cardinal Health's Controls

46. Cardinal Health's controls have been effective. Cardinal Health has terminated hundreds of pharmacies it concluded posed an unreasonable risk of diversion. Many customers to which Cardinal Health suspended shipments of controlled substances retain their DEA registrations. Moreover, DEA's own data reveals that Cardinal Health's statewide distribution of oxycodone to Florida pharmacies has not been unusually large. According to data presented by DEA in the ISO-related district court proceedings, the average sales of oxycodone to Cardinal Health's Florida pharmacy customers (other than the four pharmacies named in the February 2 Order) were significantly smaller than the average amount of oxycodone purchased by a Florida pharmacy. *See* Resp. Exh. 60; *see also* Resp. Exh. 37 (showing that Cardinal Health was the second largest distributor of oxycodone in Florida, and that its distribution of oxycodone in Florida was not significantly greater than that of the third largest distributor).

IV. Cardinal Health's Anti-Diversion Efforts In Florida And The Four Named Pharmacies

A. Targeted Attention To Florida In 2009-2010

47. Cardinal Health has recognized that the problem of controlled substance diversion is particularly acute in Florida. In 2009, Cardinal Health conducted an in-depth analysis of its customers located in Broward, Dade, and Palm Beach Counties—the areas that, at the time, comprised the epicenter of the diversion problem in Florida. This detailed analysis was conducted using a combination of analytics and traditional investigative techniques. Cardinal Health applied a quantitative model to identify pharmacies that were considered at highest risk of potential diversion and then took appropriate action.

48. Then, in the fall of 2010, I met with Ms. Boockholdt of DEA and she indicated that she believed Cardinal Health should review its Florida customers because of the growing diversion problem in Florida. Cardinal Health had already planned to investigate four of its largest retail independent pharmacy customers in Florida. Based on this information from Ms. Boockholdt, Cardinal Health performed site visits at an additional 49 of those customers in October 2010. These customers were identified using Cardinal Health's advanced analytics. This "blitz" involved not only Cardinal Health's core team of investigators, but also senior QRA pharmacists. As a result of these site visits that occurred in October 2010, Cardinal Health ceased distributing controlled substances to five customers. The decision to terminate these customer accounts was reported to DEA and the Florida Board of Pharmacy.

B. Efforts Specific To The Four Pharmacies

49. DEA's February 2, 2012 order to show cause and immediate suspension order ("February 2 Order") and DEA's Prehearing Statement assert that Cardinal Health's sales of controlled substances to two independent retail pharmacies (Caremed Health Corp. ("Caremed")

and Gulf Coast Medical Pharmacy ("Gulf Coast")) and to two CVS pharmacies (store 219 and store 5195) support DEA's conclusion that continued registration of the Lakeland facility is inconsistent with the public interest. As described in more detail below, however, these past sales do not reflect a failure to conduct meaningful due diligence. For each store, Cardinal Health monitored purchases of oxycodone and conducted investigations to attempt to determine whether controlled substances were being diverted into other than legitimate medical channels. When Cardinal Health discovered evidence that signaled that it could no longer conclude that controlled substances it distributed to the two independent retail pharmacies were not likely to be diverted into illegitimate channels, it terminated distribution of controlled substances to those pharmacies. Indeed, Cardinal Health had already ceased distributing to both Caremed and Gulf Coast (on September 26, 2011 and October 5, 2011, respectively) prior to the issuance of DEA's Administrative Inspection Warrant ("AIW") on October 25, 2011. *See* Resp. Exh. 73 (Caremed termination); Resp. Exh. 74 (Gulf Coast termination); Resp. Exh. 75 (AIW). And when DEA indicated that it believed that CVS stores 219 and 5195 posed an unreasonable risk of potential diversion—by including them in the February 2 Order—Cardinal Health terminated distribution of controlled substances to those stores as well within hours of the Order being served.

1. Caremed

50. In November 2008, the co-owner and pharmacist in charge of Caremed filled out Cardinal Health's KYC form, and answered all questions satisfactorily. *See* Resp. Exh. 42 at 135-141.

51. In response to a threshold event in January 2010, Cardinal Health's QRA pharmacist reviewed and approved Caremed's ordering history. *See* Resp. Exh. 42 at 119. Based on his review, the QRA pharmacist concluded that Caremed's January 2010 order was "not unreasonable" and requested a site visit to verify the growth in Caremed's order history.

52. While the request for a site visit was pending, Caremed placed orders that triggered threshold events in late February and late March 2010. *See* Resp. Exh. 79 at 2; *see also* Resp. Exh. 42 at 97, 117-118. The QRA record reflects that, while the March 2010 order was being held, QRA's Director of Supply Chain Integrity and Regulatory Operations, Steve Morse, discussed the growth in Caremed's ordering of controlled substances with Caremed's pharmacist in charge. *See* Resp. Exh. 42 at 106. Following up on that conversation, Caremed's pharmacist in charge faxed a letter to Mr. Morse stating the reasons for increased controlled substances threshold limits. *See* Resp. Exh. 42 at 106. In that letter, the pharmacist explained that many stores in the area, Bonita Springs, Florida, had stopped carrying controlled substances, that many physicians were requiring patients to use only one pharmacy for controlled substances, and that those physicians were referring their patients to Caremed because it specialized in pain management. *See* Resp. Exh. 42 at 106. The pharmacist also reported that Cardinal Health and another distributor, API, were the pharmacy's primary sources for controlled substances. Along with the letter, the pharmacist submitted a drug dispensing report reflecting the pharmacy's dispensing data. *See* Resp. Exh. 42 at 107-116. Cardinal Health's SOM data reflects that, two weeks later, Caremed's threshold was raised from 26,000 dosage units per month to 32,001 dosage units of oxycodone per month because "customer supplied dispense data." Resp. Exh. 76. The same SOM entry also reflects that a "site visit [had been] scheduled." *Id.*

53. In May 2010, Cardinal Health's QRA investigator performed an on-site visit. The visit confirmed prior reports that the pharmacy is located "[i]nside the Bonita Community Health Center, on the 1st floor lobby[.]" *See* Resp. Exh. 42 at 93. The investigator also obtained a drug dispensing report covering the period from May 2009 through April 2010. *See* Resp. Exh. 42 at 76-81. The site visit report shows that Caremed reported filling, on average, 150 prescriptions

per day at the time of the site visit, but up to 250 "when winter residents are here." *See* Resp. Exh. 42 at 94. The percentage of cash sales was only 5%. *See* Resp. Exh. 42 at 95. The percent of controlled substances prescriptions was about 40% for the pharmacy, which the pharmacist in charge explained on the ground that the majority of residents were elderly with injuries or cancer. *See* Resp. Exh. 42 at 94. The investigator concluded that the pharmacy posed a low risk of diversion because the substantial elderly population served by the pharmacy justified the volume of its oxycodone prescriptions. *See* Resp. Exh. 42 at 73.

54. When Caremed's monthly purchases of oxycodone increased between June 2010 and December 2010, Cardinal Health's QRA pharmacist initially approved three threshold adjustments, since a "site visit [had been] completed" in recent months with "no evidence of diversion" and Caremed had been "rated low risk" by Cardinal Health's investigators. Resp. Exh. 76. As the increases continued, however, the QRA department took action to investigate: It first obtained a drug dispensing report in November 2010, Resp. Exh. 42 at 51-53, and then sent an on-site investigator to the pharmacy on January 13, 2011, *id.* at 32. In connection with the site visit, the investigator obtained another drug dispensing report. Resp. Exh. 42 at 41-48. The pharmacy reported that 35% of its total number of prescriptions were for controlled substances, and only 10% of its prescriptions were paid for in cash. Resp. Exh. 42 at 36-37. The investigator, therefore, indicated that Caremed was a low risk for diversion. Resp. Exh. 42 at 32.

55. Following the site visit in January 2011 that resulted in a "low risk" ranking, Cardinal Health raised Caremed's threshold on February 9, 2011, and concluded, after review by the QRA pharmacist, that a few subsequent orders that exceeded thresholds were not unreasonable. *See* Resp. Exhs. 76, 79.

56. In September 2011, however, Cardinal Health conducted another site visit. During the September 2011 inspection, the Cardinal Health investigator discovered that the pharmacy was not actually filling any oxycodone prescriptions issued by the pain management physicians located in the same building. *See* Resp. Exh. 42 at 21. In addition, the investigation revealed that cash sales had risen to 40% of total sales and that controlled substance sales had risen to 45% of total sales. *See* Resp. Exh. 42 at 21. Cardinal Health thus could no longer conclude that the controlled substances it distributed to the pharmacy were not likely to be diverted.

57. Cardinal Health terminated sales of controlled substances to Caremed on September 26, 2011, well before DEA's administrative inspection of Cardinal Health. *See* Resp. Exh. 73. Cardinal Health immediately reported the suspension of sales to DEA. *See* Resp. Exh. 73.

2. Gulf Coast

58. In June 2008, the owner of Gulf Coast filled out Cardinal Health's KYC questionnaire, and answered all questions satisfactorily. *See* Resp. Exh. 43 at 156-162.

59. Cardinal Health compliance personnel conducted site visits of the pharmacy in August 2008, April 2009, December 2009, October 2010, and February 2011. At each inspection, the pharmacy provided legitimate reasons for the quantities of controlled substances it purchased from Cardinal Health.

60. Cardinal Health's QRA department conducted its first site visit of Gulf Coast in August 2008, shortly after a threshold event. *See* Resp. Exh. 43 at 141-147; 154-155. The site visit report indicates that Gulf Coast filled an average of 300 prescriptions per day and that it was located "inside a medical office building, next to a hospital and two other medical office buildings, all in one large parking area." Resp. Exh. 43 at 145. It also reported that several hundred physicians in all specialized fields operated within the complex and that the hospital had permitted the pharmacist in charge to place pharmacy flyers in all the rooms. *See* Resp. Exh. 43

at 145. The site visit report also noted that nurses reportedly brought outpatients from the medical facility to the pharmacy to pick up their prescriptions. *See* Resp. Exh. 43 at 145.

61. In mid-April 2009, a threshold event caused the QRA pharmacist to review the file and conclude that the threshold for Gulf Coast could not be raised without a site visit. *See* Resp. Exh. 43 at 128-131. The pharmacy owner reached out to Cardinal Health, explaining, among other things, that the medical facility where the pharmacy was located had increased from 100 beds to 400 beds. *See* Resp. Exh. 43 at 129.

62. The QRA investigator conducted a site visit at the end of April 2009. He confirmed that there had been a tremendous growth within the hospital and the surrounding medical clinics within the complex. *See* Resp. Exh. 43 at 117-123. The investigator noted that the high incidence of controlled substance sales he observed at the pharmacy was "due to [the] hospital and 3 pain clinics in [the] office building." *See* Resp. Exh. 43 at 117. He also reported that, during the pre-visit investigation, he learned from Cardinal Health's salesperson in charge of the account, Lenny Moro, that Mr. Moro had learned some troubling hearsay about Gulf Coast from a competitor. Resp. Exh. 43 at 117, 122, 143. The Cardinal Health investigator, however, did not find any concrete evidence of a problem. *See* Resp. Exh. 43 at 123. Nonetheless, he contacted a local DEA Diversion Investigator and informed him of what he had found. Resp. Exh. 43 at 123. The local DEA Diversion Investigator, Kenneth Boggess, told the Cardinal Health investigator that he would follow up and review the pharmacy's prescriptions, *see* Resp. Exh. 43 at 123—an investigative tool that is not available to Cardinal Health. I assume that Investigator Boggess would have informed Cardinal Health if DEA had concluded that this pharmacy presented a problem. Cardinal Health did not hear back from the DEA Investigator.

63. On October 5, 2010, Cardinal Health conducted another site visit of Gulf Coast. Prior to the visit, the owner of Gulf Coast had explained that, given the location of the pharmacy, its ordering pattern changed depending upon the patient population. *See* Resp. Exh. 43 at 57. Cardinal Health had also been informed that a pain management doctor, Dr. Kenneth Galang, had recently opened a practice in the vicinity of the pharmacy. *See* Resp. Exh. 43 at 57. Cardinal Health had researched the background of this physician and verified that he held a valid DEA registration and had no disciplinary record or public complaint on file. *See* Resp. Exh. 43 at 48, 50. The physician was listed in the site visit report as one of the primary prescribers of controlled substances dispensed by the pharmacy. Resp. Exh. 43 at 30.

64. At the same time, the visit raised some questions. The QRA investigator, Vincent Moellering, ranked the pharmacy as presenting a high risk of diversion. That ranking appeared to be based on two primary factors. First, the site visit report indicated that the salesperson in charge of Gulf Coast's account, Lenny Moro, had seen groups of young people in their 20s and 30s arrive at the pharmacy to have prescriptions filled. *See* Resp. Exh. 43 at 31. Mr. Moellering's notes, however, indicate that he observed only "one group of three young customers who came in together and left the pharmacy together (2 males and 1 female)" during his visit. *See* Resp. Exh. 43 at 32. Cardinal Health had no way to know whether the prescriptions filled by any particular customer were for controlled substances. Moreover, I understand that Steve Morse, Mr. Moellering's supervisor, visited the pharmacy twice and did not see this type of activity. Second, Mr. Moellering raised a concern that Gulf Coast's assertion that it filled prescriptions only for local customers was not true. He proposed contacting DEA to resolve this issue. *See* Resp. Exh. 43 at 32. Contacting DEA would not likely have helped resolve Mr. Moellering's concern about out-of-area patients. DEA does not receive data in the

ordinary course on the addresses of pharmacies' patients, and DEA would not have shared with Cardinal Health any patient data it did have. Nor could Cardinal Health have acquired that data directly from the pharmacy because of patient privacy concerns.

65. The October 5, 2010 site visit thus raised some potential concerns but did not appear to be dispositive. Cardinal Health decided to obtain from Gulf Coast a list of its top prescribers and verify that those prescribers were local to the pharmacy's area. Resp. Exh. 43 at 25-26. Based on his review of the prescriber list provided by Gulf Coast, Steve Morse concluded that the primary prescribers of controlled substances were local, with the exception of one orthopedic surgeon. Resp. Exh. 43 at 25. On the basis of this information, Mr. Morse concluded in November 2010 that Mr. Moellering's "high risk" recommendation was not warranted and that a "medium risk" assessment was more appropriate. Cardinal Health marked the pharmacy for closer monitoring. *See* Resp. Exh. 43 at 25.

66. In February 2011, Steve Morse conducted a follow-up site visit to Gulf Coast. *See* Resp. Exh. 43 at 22. According to Mr. Morse's report, Gulf Coast represented that it vetted prescribers of controlled substances as follows:

- Checks licensure through the Florida Department of Health website and searches for disciplinary actions;
- Checks DEA registration numbers through DEA's website or one linked to DEA's information;
- Checks addresses and phone numbers of practitioners through 411 reverse directory;
- Verifies all Schedule II controlled substances prescriptions with the prescribing practitioner; and
- Limits sales of controlled substances to prescribers located in Lee County.

See Resp. Exh. 43 at 22.

67. The owner of Gulf Coast also informed Mr. Morse that he filled prescriptions for controlled substances only for Lee County residents, with the exception of patients discharged from the emergency room. *See* Resp. Exh. 43 at 22.

68. Cardinal Health also received a letter dated February 8, 2011 from Dr. Andrew Esch, a palliative care specialist who had joined the Lee Memorial Health System as Medical Director of the Q-Life program in September 2010. *See* Resp. Exh. 43 at 23. The letter stated that Dr. Esch "will be sending [his] patients exclusively to Jeff Green at Gulf Coast Medical Pharmacy." Resp. Exh. 43 at 23. Accordingly, Dr. Esch stated that he "will need all C2, C3, C4 and C5 brands available at our exposure for all four hospitals and our outpatient clinic for Lee County area." Resp. Exh. 43 at 23.

69. In the fall of 2011, Mallinckrodt communicated to Cardinal Health that it had decided to discontinue chargebacks for sales to the pharmacy. Mallinckrodt's report prompted a reassessment by the QRA team of information about Gulf Coast that Cardinal Health had obtained through prior investigations, as well as a review of recent purchasing data on the pharmacy. Cardinal Health also obtained information from Mallinckrodt indicating that the pharmacy had purchased more oxycodone than Cardinal Health had sold to it. It thus appeared that Gulf Coast was purchasing oxycodone from another distributor as well.

70. Around the same time, Cardinal Health came to doubt the truthfulness of other representations made by the owner of Gulf Coast. The owner of Gulf Coast had suggested to Cardinal Health's QRA investigators that the Sheriff's Office had supported the consolidation of controlled substances prescriptions from the four Lee Memorial Health System facilities through Gulf Coast. Cardinal Health requested that Gulf Coast provide verification of any such support.

In response, the pharmacy provided a letter from the local Sheriff's Office. Resp. Exh. 43 at 18-19. That letter, however, did not address the issue raised by Cardinal Health. Cardinal Health concluded that it could no longer trust the information provided by Gulf Coast. Cardinal Health terminated sales of controlled substances to the pharmacy on October 5, 2011, well before DEA's administrative inspection, and reported that termination to DEA. Resp. Exh. 74.

3. CVS 219 and CVS 5195

71. Cardinal Health conducted appropriate due diligence with respect to CVS stores 219 and 5195.

72. Cardinal Health repeatedly investigated, through CVS's pharmacists in charge and through CVS's corporate offices, orders for controlled substances placed by CVS 219 and CVS 5195.[3] *See generally* Resp. Exh. 44; Resp. Exhs. 52, 53 (containing examples of review of threshold events relating to CVS 219 and CVS 5195). For example, Cardinal Health initiated the following inquiries:

- In March 2009, CVS 219 placed an order that Cardinal Health's Compliance Officer for the Lakeland facility believed warranted additional review. A conversation with the pharmacist in charge at CVS 219 revealed that the order was in fact a mistake. *See* Resp. Exh. 47.

[3] CVS does not order all of its prescription drugs from Cardinal Health because CVS is self-warehousing. Self-warehousing means that CVS owns and operates its own warehouse from which it distributes products other than Schedule II drugs and certain branded drugs to its retail pharmacy locations. Cardinal Health regularly supplies CVS with Schedule II controlled substances and limited branded prescription drugs. Occasionally, CVS will order other drugs, including Schedule III-V controlled substances, from Cardinal Health on an as-needed basis; but CVS typically obtains these products from another source. Therefore, Cardinal Health's distribution of drugs to CVS tends to be heavily weighted toward Schedule II controlled substances, and the proportion of Schedule II controlled substances in relation to all pharmaceutical products delivered by Cardinal to CVS tends to be greater than with other pharmacies by virtue of the meaningful self-distribution by CVS of non-controlled medications to its stores.

- In June 2009, a Cardinal Health representative reached out twice to a CVS representative in response to certain orders placed by CVS 219 and as a follow-up to conversations the Cardinal Health representative had with the pharmacist in charge of CVS 219. The CVS representative inquired with CVS's loss prevention department, which reported that the orders placed by CVS 219 were consistent with the pharmacy's dispensing. *See* Resp. Exh. 48.
- In January 2010, a Cardinal Health representative inquired with the pharmacist in charge of CVS 219 in connection with pending orders for oxycodone products. *See* Resp. Exh. 49. As part of that conversation, the Cardinal Health representative discussed the obligations of the pharmacist with respect to filling prescriptions for controlled substances. *See* Resp. Exh. 49. On the same day, the Cardinal Health representative also followed up on her conversation with the pharmacist in charge by inquiring with a CVS representative. *See* Resp. Exh. 50. The CVS representative responded approximately two weeks later and reported that CVS's loss prevention department had approved those orders. *See* Resp. Exh. 50.

73. In the late summer or early fall of 2010, Cardinal Health identified through its SOM program oxycodone ordering patterns at several CVS stores in Florida, including the two CVS stores named in the ISO, that warranted explanation. At a meeting with CVS I attended in late August 2010, Cardinal Health communicated to CVS its concerns. CVS indicated it would look into the matter. In response, CVS informed Cardinal Health that its loss prevention department had reviewed the stores' activities and that it had been closely monitoring store CVS 219 for a couple of weeks. *See* Resp. Exh. 51. CVS's loss prevention department also reported that none of the stores at issue had showed significant shifts in their ordering patterns. *See* Resp. Exh. 51.

CVS also noted that the company had a new attorney working with DEA on diversion-related issues. *See* Resp. Exh. 51. CVS explained that Florida had been cracking down on illegitimate pain clinics and that those efforts were having the effect of driving legitimate demand for controlled substances to the CVS stores. *See* Resp. Exh. 51.

74. Around the same time, in October 2010, Cardinal Health was conducting the widespread investigation of independent retail pharmacies I described earlier in this declaration. *See* ¶ 48. As a result, several QRA employees—including QRA pharmacist Christopher Forst—were conducting site visits in Florida. While it was not Cardinal Health's policy to conduct investigative site visits at chain pharmacies such as CVS, I asked Christopher Forst to conduct a visit of store CVS 219. *See* Resp. Exh. 54. In response to my inquiry, Mr. Forst confirmed that there were no signs of diversion at CVS 219:

> Yes, nothing, not one car from out of state. The only thing I did notice is that they are located on the corner of a shopping area that contained a large grocery store that looks like it had recently closed. This store had a pharmacy inside of it. Maybe I was there at the wrong time, it was around 2 p.m. I think Vince needs to do a couple drive by's on a Tuesday or Wednesday. Monday didn't seem abnormal and the customers inside were appropriate for the area. I will say this store did have a lot of personnel in the pharmacy department. More than I have seen in any of the other CVSs I have visited.

Resp. Exh. 54.

75. Cardinal Health continued to work diligently with CVS to investigate the ordering of controlled substances by certain CVS Florida stores. On December 2, 2010, I attended a subsequent meeting with CVS to discuss Cardinal Health's concerns about the volume of controlled substances ordered by certain CVS pharmacies. On January 6, 2011, CVS sent Cardinal Health a letter outlining its investigation of additional Florida CVS stores we had identified. *See* Resp. Exh. 55 at 1. The letter informed Cardinal Health that "CVS [had]

undertaken actions to address [Cardinal Health's] concerns about those specific pharmacies and to address suspicious ordering and dispensing generally." Resp. Exh. 55 at 1. The letter also informed Cardinal Health that "CVS [had] distributed guidelines that reinforce the company's position that pharmacists use their professional judgment when determining whether to fill prescriptions. The guidelines identify inappropriate prescription-seeking behavior and advise pharmacists how to minimize risk of dispensing for other than legitimate prescriptions." Resp. Exh. 55 at 1. In the letter, CVS reported that "CVS representatives also met with Drug Enforcement Administration and Florida Department of Health investigators regarding dispensing issues in Florida." Resp. Exh. 55 at 1.

76. The letter also identified CVS's investigations of specific Florida stores, noting that teams of CVS Pharmacy Supervisors and Regional Loss Prevention Managers had visited several CVS Florida stores, interviewed pharmacy staff, and reviewed controlled substance ordering, receiving and dispensing procedures, controlled substance records and reports, and security. *See* Resp. Exh. 55 at 1. The letter reported that the teams had "found no evidence of controlled substance diversion or significant losses." *See* Resp. Exh. 55 at 1. It concluded that CVS was "confident that pharmacists and their staffs at these pharmacies understand how to minimize the risk of dispensing controlled substances, particularly opioids for pain management, for non-legitimate purposes." *See* Resp. Exh. 55 at 1. The letter then assured Cardinal Health that CVS was "comfortable with Cardinal continuing to ship controlled substances to these pharmacies." *See* Resp. Exh. 55 at 2.

77. On October 12, 2011, I received further reassurances from CVS that its corporate office had investigated CVS's Florida locations, including one of the locations mentioned in the ISO. In an email following up on a prior conversation, Karen Gibbs of CVS informed me:

> As we discussed, our field management undertook a thorough review of Stores 5146, 5195 and 2848. I spoke with each team after the review. They did not find evidence of diversion, fraudulent prescriptions, or other inappropriate activity. We feel comfortable that Cardinal can continue its oxycodone shipments to these stores.

Resp. Exh. 56.

78. On October 18, 2011, DEA served AIWs on CVS 219 and CVS 5195. On October 26, 2011, DEA served an AIW on Cardinal Health's Lakeland facility. This inquiry prompted Cardinal Health to review its prior reliance on CVS' investigations of CVS 219 and CVS 5195, and to take further action. For example, in November and December 2011, Cardinal Health significantly lowered the thresholds applicable for CVS 219's and CVS 5195's oxycodone purchases.

79. Moreover, in the fall of 2011, CVS had decided to stop filling prescriptions for Schedule II controlled substances written by 22 Florida doctors. Resp. Exh. 57 (news article regarding termination of doctors). This decision became effective on November 21, 2011. Resp. Exh. 58, ¶ 32 (sworn declaration of CVS employee). *See generally* Resp. Exh. 59, ¶ 22 (sworn declaration of CVS employee). DEA was informed of this decision before that date. *See* Resp. Exh. 77 (email from CVS's counsel to Barbara Boockholdt). Based on information provided by CVS at the time, these 22 doctors had accounted for at least 64% of the oxycodone prescriptions filled by CVS 219 and CVS 5195 between May 2011 and October 2011. According to a sworn declaration submitted by CVS in federal court, during the longer period of January 1, 2011 through November 21, 2011, these 22 physicians accounted for 69% and 71% of the oxycodone prescriptions filled by CVS 219 and CVS 5195, respectively. *See* Resp. Exh. 78, ¶¶ 7-8.

80. The volume of oxycodone ordered by CVS 219 and CVS 5195 in October, November, and December dropped precipitously:

- CVS Store 219, according to ARCOS information disclosed by DEA in related court proceedings, received from the Lakeland facility about 247,000 dosage units of oxycodone in August 2011, about 234,000 dosage units in September 2011, about 159,000 dosage units in October 2011, about 42,000 dosage units in November 2011, and about 37,000 dosage units in December 2011; and
- CVS Store 5195, according to ARCOS information disclosed by DEA in related court proceedings, received from the Lakeland facility about 126,000 dosage units of oxycodone in August 2011, about 112,000 dosage units in September 2011, about 63,000 dosage units in October 2011, about 15,000 dosage units in November 2011, and about 10,000 dosage units in December 2011.

Resp. Exhs. 45-46.

81. On February 3, 2012, DEA served its February 2 Order on the Lakeland facility. *See* Resp. Exh. 63. The February 2 Order identified CVS 219 and CVS 5195 among the four stores that DEA believed had been "engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose." Resp. Exh. 63 at 2; *see also* Resp. Exh. 64 (ISO for CVS 219); Resp. Exh. 65 (ISO for CVS 5195). Consistent with its pledge to terminate any customer that DEA believes poses an unreasonable risk of potential diversion, on February 3, 2012, Cardinal Health immediately terminated sales of controlled substances to CVS 219 and CVS 5195 from all its distribution centers.

82. In my opinion, Cardinal Health's conduct with respect to CVS stores 219 and 5195 was reasonable under the circumstances. CVS is one of the nation's largest pharmacy chains. As explained above, Cardinal Health has historically approached its due diligence of chain pharmacies in a way that is similar to but distinct from independent retail pharmacies, in that

Cardinal Health relies more heavily on the chain's corporate department. With respect to CVS in particular, I never had any basis to doubt the truth and soundness of the representations made to Cardinal Health by CVS's corporate offices.

83. To the contrary, several considerations suggested to me that the representations made by CVS's corporate department were made in good faith and were reliable. First, the information Cardinal Health receives from the corporate office of CVS is not coming from a pharmacist who may be engaged in misconduct. Second, pharmacists are ultimately responsible for filling prescriptions, and chain pharmacists do not have the same direct and substantial financial interests in filling prescriptions as retail independent pharmacists who often own the pharmacy do. Third, CVS, as a large corporation, has a corporate interest in operating pharmacies that comply with DEA's regulations. Fourth, I am personally acquainted with many of CVS's current and former pharmacists, including the following individuals: Orren Peacock (retired), former President of the National Association of Boards of Pharmacies and the Texas State Board of Pharmacy; Michael Ayotte, former member of the Virginia Board of Pharmacy; Carl H. (Fritz) Hayes, former Chairman of the Florida Board of Pharmacy; Robert Parrado, former President of the Florida Board of Pharmacy; and Richard Kolezynski, member of the Ohio State Board of Pharmacy, with whom I currently serve. It is my personal and professional judgment that these individuals have demonstrated a commitment to their professional, corporate, and societal responsibilities. Fifth, CVS has rarely failed to respond when the QRA team or I asked for information about a particular store or order. Sixth, in 2008, CVS and Cardinal Health conducted a webinar during which CVS discussed, among other things, its loss prevention protocols. This presentation led me to believe that CVS had the capability and commitment to investigate potential diversion.

* * *

84. Cardinal Health continues to strive to enhance its SOM system and is committed to doing its part to prevent diversion of controlled substances into other than legitimate medical channels. The company has devoted tremendous resources to this endeavor and will continue to do so going forward. Although there are things that Cardinal Health could have done differently with respect to the four pharmacies named in the February 2 Order, it is my belief that the company acted reasonably and diligently to address an ever-evolving problem posed by prescription drug diversion.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 13, 2012.

Michael A. Moné